

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of hydro-alcoholic extract of Capsella bursa Pastoris on postpartum pain

Protocol summary

Study aim

Effect of hydro-alcoholic extract of Capsella bursa Pastoris on postpartum pain

Design

Randomized triple blinded clinical trial with parallel groups

Settings and conduct

In a randomized, triple-blind, randomized clinical trial women who fulfill the inclusion criteria and reported postpartum pain score more than four will be enrolled in study. The intervention group will receive mefenamic acid capsule 50 mg, every 6 hours for a maximum of 4 doses for 24 hours plus 10 sublingual drops of hydroalcoholic extract of Capsella bursa Pastoris containing 500 mg of the extract. Control group will receive mefenamic acid capsule 250 mg, every 6 hours for a maximum of 4 doses for 24 hours plus 10 drops placebo (distilled water) sublingually.

Participants/Inclusion and exclusion criteria

Mothers of normal vaginal delivery and gestational age of 42-37 weeks, with a single live infant who borned with cephalic presentation, weight of 2500-4000gr will be enrolled in study. Mothers with prolonged labor or assisted or analgesic delivery and severe bleeding, drug addiction, or with systemic disease, as well as patients with grade 3 and 4 perineal rupture will be excluded from the study.

Intervention groups

Intervention group (sublingual drops of hydro-alcoholic extract of Capsella bursa Pastoris and mefenamic acid capsule 250mg) Control group (recipient of sublingual placebo drop and mefenamic acid capsule 250mg)

Main outcome variables

Severity of postpartum pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191002044948N1**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **retrospective**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Maryam Keshavarzinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3522 5663

Email address

maryam.keshavarzinejad1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-06, 1398/04/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hydro-alcoholic extract of Capsella bursa Pastoris on postpartum pain

Public title

Effect of hydro-alcoholic extract of Capsella bursa Pastoris on postpartum pain	
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Normal Delivery The gestational age is 37-42 weeks Live single baby with cephalic presentation The fetal weight is 2500-4000 Moderate or severe pain based on Pain Ruler
Exclusion criteria:	Any problems that require emergency action such as maternal bleeding Severe bleeding Difficult and prolonged childbirth and use of tools analgesics for childbirth Drug addiction or psychotropic drugs Systemic disease Perineal ruptures grade 3 and 4
Age	No age limit
Gender	Female
Phase	3
Groups that have been masked	• Participant • Investigator • Data analyser
Sample size	Target sample size: 100
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization perform by an independent trial center. If a patient fulfill the inclusion criteria and has signs informed consent, the researcher contacts the trial center. A quadratic permutation block method used. Subjects in blocks 1, 3 and 5 entered into the control group and subjects in blocks 2, 4 and 6 entered into the intervention group and simple randomized table used to select blocks. To assign patients to study groups the random assignment sheet will be used by trained personnel.
Blinding (investigator's opinion)	Triple blinded
Blinding description	The placebo is similar to the drug regarding shape of container, color, and volume and the researcher and patient will not aware of the type of extract or placebo. The outcome assessor do not know the types of the patient's intervention and only has the patient's specific code. In addition, statistician will not aware of the study groups.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Shahid Beheshti University of Medical Sciences
Street address	University Square., Nilufar Ave., Maryam Street., Damqan Town., Plaque21
City	Damqan
Province	Semnan
Postal code	3671639846
Approval date	2017-07-01, 1396/04/10
Ethics committee reference number	IRSBMU.PHNM.1396.746
Health conditions studied	
1	
Description of health condition studied	postpartum pain
ICD-10 code	G89.18
ICD-10 code description	Other acute postprocedural pain
Primary outcomes	
1	
Description	Severity of pain
Timepoint	Every 1 hour up to six hours after intervention and then every 6 hours up to 24 hours after intervention
Method of measurement	Pain Ruler
Secondary outcomes	
1	
Description	Duration of pain
Timepoint	One hour after taking the drug
Method of measurement	In hours and minutes
Intervention groups	
1	
Description	

The intervention group received mefenamic acid capsule 250 mg, every 6 hours for a maximum of 4 doses for 24 hours plus 10 sublingual drops of hydroalcoholic extract of Capsella bursa Pastoris containing 500 mg of the extract.

Category

Treatment - Drugs

2

Description

Control group received mefenamic acid capsule 250 mg, every 6 hours for a maximum of 4 doses for 24 hours plus 10 drops placebo (distilled water) sublingually.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Maryam keshavarzinejad

Street address

University Square., Nilufar Ave., Maryam Street.,
Damqan Town., Plaque21

City

Damqan

Province

Semnan

Postal code

3671639846

Phone

+98 23 3522 5663

Email

maryam.keshavarzinejad1369@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Research Assistant, School of Nursing and Midwifery

Street address

Vice-Chancellor for Research, Midwifery Nursing and
Midwifery, Third floor, Vice chancellor for research,
Shahid Rajaee Heart Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2517

Fax

+98 21 8820 2517

Email

n_kariman@yahoo.com

Web page address

https://www.sbm.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Nour sadat Kariman

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Vice-Chancellor for Research, Midwifery Nursing and
Midwifery, Third floor, Vice chancellor for research,
Shahid Rajaee Heart Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2516

Fax

+98 21 8820 2516

Email

n_kariman@yahoo.com

Web page address

https://www.sbm.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Noursadat Kariman

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Vice chancellor for research, Third floor, Vice
chancellor for research, Nursing and Midwifery
Faculty, Valiasr Ave.

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8820 2516

Fax

+98 21 8820 2516

Email

n_kariman@yahoo.com

Web page address

<https://www.sbmu.ac.ir>

City

Damqan

Province

Semnan

Postal code

3671639846

Phone

+98 23 3522 5663

Email

maryam.keshavarzinejad1369@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after unidentifiable
people

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

researchers

Under which criteria data/document could be used

Correspondence

From where data/document is obtainable

Mailing address to researcher

What processes are involved for a request to access data/document

1 month

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam keshavarzinejad

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

University Square., Nilufar Ave., Maryam Street.,
Damqan Town., Plaque21